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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,349	08/19/2003	Robert Seid	2300-1357.10 (PP01357.124)	3803
27476	7590	07/24/2006	EXAMINER	
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/643,349	SEID, ROBERT	
	<b>Examiner</b>	<b>Art Unit</b>	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31, 32, 43, 45-47 and 50-55 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31, 32, 43, 45-47 and 50-55 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/27/06</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## **Response to Applicant's Amendment**

### **Applicant's Amendments**

1) Acknowledgment is made of Applicant's amendment filed 04/25/06 and 01/27/06 in response to the non-final Office Action mailed 09/29/05. The amendment filed 04/25/06 is compliant with 37 CFR 1.121.

### **Status of Claims**

2) Claims 31, 32, 45, 46, 50, 52, 53 and 54 have been amended via the amendment filed 04/25/06.

Claims 31, 32, 43, 45-47 and 50-55 are pending and are under examination.

### **Information Disclosure Statement**

3) Acknowledgment is made of Applicant's information disclosure statement filed 01/27/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Maintained**

6) The rejection of claims 31, 32, 43, 45-47 and 50-55 made in paragraph 8 of the Office Action mailed 09/30/04 and paragraph 12 of the Office Action mailed 09/29/05 and maintained in paragraph 12 of the Office Action mailed 03/26/05 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of the U.S. Patent 6,638,513, is maintained for reasons set forth therein and herebelow. Applicant requests that the requirement for submission of a Terminal Disclaimer be held in abeyance until there is an

indication of allowable subject matter in the present application.

7) The rejection of claim 31 and those dependent therefrom made in paragraph 23 of the Office Action mailed 03/26/05 and maintained in paragraph 13 of the Office Action mailed 09/25/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein and herebelow.

Applicant points to lines 14-17 of page 14 of the specification and states that this part of the specification refers to further glycoconjugates that can be formed from the above-described MenB OS derivative fragments. Applicant points to lines 1-6 of page 11 of the specification and submits that the 'above-described' MenB OS derivative fragments refer in part to 'C<sub>3</sub>-C<sub>8</sub> acyl derivatives' that can be made by first N-deacylating native MenB in the presence of a strong base to qualitatively remove N-acetyl groups and to provide a reactive amine group in the sialic acid residue parts of the molecule. Applicant then refers to lines 25-30 of page 11 of the specification and states that 'the above-described N-acylated MenB polysaccharide derivatives' (i.e., C<sub>3</sub>-C<sub>8</sub> acyl derivatives) are fragmented and then size-fractionated to provide a substantially homogeneous population of intermediate 'sized' MenB oligosaccharide fragments for use in preparing glycoconjugates. With this, Applicant concludes that the replacement of sialic acid residue N-acetyl groups with N-C<sub>3</sub>-C<sub>8</sub> acyl groups on substantially homogenous population of oligosaccharide fragments for use in preparing glycoconjugates with or without a lipid moiety is adequately described in the application as filed. Applicant further contends that covalently attaching a C<sub>3</sub>-C<sub>16</sub> long-chain aliphatic lipid to the non-reducing end of a MenB OS glycoconjugate is described on pages 14-18 of the present application. Applicant submits that additional exemplification of the C<sub>3</sub>-C<sub>8</sub> acyl derivatives is provided at page 8, lines 1-11; page 11, lines 1-7; page 13, lines 26-34; and page 16, lines 1-22, and in the reference of EP 504,202 cited at page 8, lines 10-11 of the specification. Applicant states that the preparation of the N-propionyl derivative is described as a preferred embodiment, and not as the only embodiment.

Applicant's arguments have been carefully considered, but are not persuasive. As set forth in the rejection of record, the new matter issue is related specifically to step (c) of claim 31, which step was added to claim 31 via Applicants' amendment filed 01/03/05. See paragraph 23 of the Office Action mailed 03/26/05. The step (c) added to claim 31 is reproduced below:

(c) covalently attaching a C3-C16 long-chain aliphatic lipid to the nonreducing end of the MenB OS obtained in step (b);

Inclusion of this step (c) to claim 31 changed the scope of the claim in that, as claimed currently, step (c) involves covalent attachment of a C3-C16 long-chain aliphatic lipid to the *nonreducing* end of the MenB OS obtained in step (b). The MenB OS 'obtained in step (b)' is a homogenous sized group of MenB OS from the population of step (a) wherein said group of MenB OS has an 'average degree of polymerization (Dp) of about 10 to 20'. The population of MenB OS from step (a) has sialic acid N-acetyl groups already 'replaced' with N-C<sub>3</sub>-C<sub>8</sub> acyl groups. Lines 14-17 of page 14 of the specification do not describe the newly added step (c) of claim 31 as it relates to a substantially homogenous sized group of MenB OS wherein sialic acid N-acetyl groups are replaced with N-C<sub>3</sub>-C<sub>8</sub> acyl groups and has a Dp of 'about 10 to 20'. This part of the specification cites the reference of Mandrell *et al.* and merely states that the presence of a lipid moiety at the **reducing** ends (as opposed to the recited non-reducing end) of bacterial MenB PS (i.e., native MenB polysaccharide as opposed to the instantly recited homogenous sized MenB oligosaccharide with the N-acetyl groups already replaced with N-C<sub>3</sub>-C<sub>8</sub> acyl groups) has been demonstrated. This part of the specification does not and cannot provide descriptive support for the above-identified step (c) of claim 31. Neither lines 1-7 of page 11 of the specification, nor lines 25-30 of page 11, lines 1-11 of page 8, lines 26-34 of page 13, and lines 1-22 of page 16 of the specification pointed to by Applicant provide descriptive support for the added step (c) of claim 31. Pages 14-18 of the specification specifically provide two N-propionylated MenB OS glycoconjugate embodiments: "CONJ-3" and "CONJ-4". CONJ-3 is unrelated to the product claimed in claim 31 because CONJ-3 has lipid moieties covalently attached at the 'reducing' ends of the N-propionylated MenB OS. CONJ-4 described in paragraph bridging pages 15 and 16 and Figure 4 of the instant specification is the only MenB OS glycoconjugate embodiment of the instant application wherein C3-C16 long-chain aliphatic lipids are covalently coupled at the '**nonreducing**' termini of the MenB OS derivative fragments. The description for Figure 4 at lines 18-20 on page 6 of the specification expressly describes that CONJ-4 contains 'N-Pr-Men B OS derivative'. The descriptive support in the instant specification is thus limited to a specific MenB OS glycoconjugate embodiment, 'CONJ-4', comprising substantially homogeneous sized N-propionylated MenB OS having a C3-C16 long-chain aliphatic lipid covalently attached to the

non-reducing end of the N-propionylated MenB OS and being conjugated to a protein carrier. A glycoconjugate as specifically claimed in the amended claim 31 comprising substantially homogenous sized MenB OS having N-acetyl groups replaced with N-C<sub>3</sub>-C<sub>8</sub> acyl groups and being covalently attached to a C3-C16 long-chain aliphatic lipid at the *non-reducing* end of said MenB OS as recited, lacks descriptive support in the specification, as originally filed. The rejection stands.

### **Rejection(s) Withdrawn**

**8)** The rejection of claim 31 made in paragraph 24(a) of the Office Action mailed 03/26/05 and maintained in paragraph 14 of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**9)** The rejection of claim 32 made in paragraph 24(b) of the Office Action mailed 03/26/05 and maintained in paragraph 15 of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**10)** The rejection of claims 43 and 45-47 made in paragraph 24(f) of the Office Action mailed 03/26/05 and maintained in paragraph 16 of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

**11)** The rejection of claims 31 and 32 made in paragraph 17(a) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

**12)** The rejection of claim 50 made in paragraph 17(a) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**13)** The rejection of claim 32 made in paragraph 17(c) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

- 14)** The rejection of claims 31 and 32 made in paragraph 17(d) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.
- 15)** The rejection of claims 31 and 32 made in paragraph 17(e) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.
- 16)** The rejection of claims 31 and 32 made in paragraph 17(f) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.
- 17)** The rejection of claim 50 made in paragraphs 17(f) and 17(g) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.
- 18)** The rejection of claims 46 and 53 made in paragraph 17(h) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.
- 19)** The rejection of claims 45 and 46 made in paragraph 17(i) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to claim 45.
- 20)** The rejection of claim 52 made in paragraph 17(j) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 21)** The rejection of claim 54 made in paragraph 17(k) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 22)** The rejection of claims 43, 45-47 and 51-55 made in paragraph 17(h) of the Office Action mailed 09/29/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.
- 24)** The rejection of claims 50-55 made in paragraph 18 of the Office Action mailed 09/29/05 under 35 U.S.C. § 103(a) as being unpatentable over Jennings *et al.* (US 5,576,002 - already of

record) ('002) or Jennings *et al.* (US 5,902,586 - already of record) ('586) in view of Kitazume *et al.* (*Anal. Biochem.* 202: 25-34, 1992 - already of record) or Jennings *et al.* (*J. Immunol.* 134: 2651-2657, 1985 - already of record) and Kniskern *et al.* (US 5,847,112, filed in 1991 - already of record), Marburg *et al.* (US 5,623,057 - already of record) and Jennings *et al.* (US 5,811,102 - already of record) ('102), is withdrawn in light of Applicant's amendment to the base claim and upon consideration Applicant's arguments.

### Remarks

**25)** Claims 31, 32, 43, 45-47 and 50-55 stand rejected.

**26) THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**27)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office' Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

**28)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**29)** Any inquiry concerning this communication or earlier communications from the

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Art Unit: 1645  
July 2006

Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2006.

  
S. DEVI, PH.D.  
PRIMARY EXAMINER